IN AND BEFORE THE OKLAHOMA STATE BOARD OF MEDICAL LICENSURE AND SUPERVISION STATE OF OKLAHOMA

STATE OF OKLAHOMA, *ex rel.* OKLAHOMA STATE BOARD OF MEDICAL LICENSURE AND SUPERVISION,	)	
Plaintiff,	)	
v.	)	**Case No. 19-07-5783**
SHMUEL SHAPIRA, M.D. LICENSE NO. MD 30917,	)	
Defendant.	)	

VERIFIED COMPLAINT

The State of Oklahoma, *ex rel.* Oklahoma State Board of Medical Licensure and Supervision ("Board"), for its Verified Complaint against Shmuel Shapira, M.D. ("Defendant"), alleges and states as follows:

I. JURISDICTION

1. The Board has jurisdiction over the subject matter and is a duly authorized agency of the State of Oklahoma empowered to license and oversee the activities of physicians and surgeons in the State of Oklahoma. 59 O.S. § 480, *et seq.* and Okla. Admin. Code 435:5-1-1 *et seq*.

2. In Oklahoma, Defendant holds medical license no. 30917, issued in 2014.

3. The acts and omissions complained of herein were made while Defendant was licensed to practice medicine by the State of Oklahoma.

II. ALLEGATIONS OF UNPROFESSIONAL CONDUCT

4. This action arises out of disciplinary action taken by the Virginia Board of Medicine resulting in a Consent Order, entered on July 23, 2020, wherein Defendant was REPRIMANDED and PERMANENTLY RESTRICTED from performing invasive cardiac procedures, thereby permanently limiting his practice to medical cardiology in the State of Virginia.

5. The *Consent Order* recited the relevant history in its "Findings of Fact and Conclusions of Law." It concluded that Defendant violated Virginia Code§ 54.l-2915(A)(3), (4), (13), and (16) in his care and treatment of Patients A-E from approximately August 2017 through May 2019. Specifically, Defendant admitted the following unprofessional conduct:

a. Intentional or negligent conduct in the practice of any branch of the healing arts that causes or is likely to cause injury to a patient or patients, in violation of Virginia Code 54.1-2915(A)(3).

b. Mental or physical incapacity or incompetence to practice his profession with safety to his patients and the public, in violation of Virginia Code 54.1-2915(A)(4).

c. Conducting his practice in such a manner as to be a danger to the health and welfare of his patients or to the public, in violation of Virginia Code 54.1-2915(A)(13).

d. Performing any act likely to deceive, defraud, or harm the public, in violation of Virginia Code 54.1-2915(A)(16).

6. The *undisputed* facts, presented in the Virginia Consent Order, are as follows:

a. In the one-year period from approximately September 2017 to September 2018, Patients A, B, and C, in whom Dr. Shapira surgically implanted pacemaker/AICD (automated implantable cardioverter defibrillator) devices, developed pacemaker/AICD site infections, each within approximately three to seven weeks of the pacemaker/AICD insertion surgeries. Due to the resultant infections, Patients A, B, and C required subsequent hospitalization and medical care including, but not limited to, surgical removal of the devices and antibiotic treatment.

b. On or about October 15, 2018, to address concerns relating to these pacemaker/AICD site infections, Dr. Shapira entered into a performance improvement plan ("PIP") with the Virginia hospital {"hospital") where he performed said surgeries on Patients A, B, and C. This PIP required a plastic surgeon to proctor Dr. Shapira and observe his technique during the performance of three or more pacemaker/AICD surgeries. During/after said proctorship, this plastic surgeon recommended changes in Dr. Shapira's surgical techniques/procedures, including but not limited to, requiring patients to undergo pre-surgical skin antiseptic preparation, and that Dr. Shapira use a different suture material for wound closure, perform a sharper dissection with less pulling apart of the tissue with his hands, and use glue in addition to stitches to close incisions, to create a tighter seal to keep germs out after closure.

c. On or about October 19, 2018, during the course of the PIP, Dr. Shapira performed pacemaker/AICD insertion surgery on Patient E. During this surgery, Dr. Shapira experienced difficulty inserting the pacemaker wires. On his first attempt to insert the wires, Dr. Shapira recognized pulsatile red blood, causing him to note that he had erroneously entered Patient E's subclavian artery, and he withdrew the wires. On his second attempt, Dr. Shapira asserted that he did not observe the same arterial indications, and continued advancing the wires. Despite this assertion, Dr. Shapira erroneously advanced the device's three wires, sheaths and leads into Patient D's [sic] left subclavian artery (instead of through the left subclavian vein), advanced the right ventricular defibrillator lead into the aortic valve, and screwed the lead into the wall of the left ventricle. After the device was implanted as such, Dr.

Shapira performed angiography, which showed that all of the leads had been erroneously placed in the left system of the heart. Now recognizing that be improperly placed the pacemaker/AICD, Dr. Shapira removed the device, wires, sheaths and leads, causing three puncture holes in Patient E's left subclavian artery. Dr. Shapira called in an interventional radiologist and a vascular surgeon, who inserted a left subclavian covered stent in an attempt to seal the three puncture holes. Post-surgery, Patient E remained unresponsive, and head and neck CT scans showed that she suffered an acute, intra-arterial thrombus, resulting in a stroke. Later that day, Patient E was transferred to another Virginia hospital where she underwent, unsuccessfully, neuro-interventional surgery to remove the thrombus. The following day, Patient E expired.

d. Subsequently, Dr. Shapira voluntarily refrained for more than thirty days from performing pacemaker/AICD insertions, as well as from performing any procedure requiring subclavian access.

e. On November 19, 2018, Dr. Shapira agreed to an addendum to the PIP that required another practitioner to proctor five or more regular pacemaker/AICD insertions. Subsequently, this pacemaker/AICD proctorship was suspended to allow Dr. Shapira to obtain additional training. During the suspension of this additional proctorship requirement, a "serious patient care concern" arose, as detailed below.

f. On or about May 27, 2019, while performing a cardiac catheterization on Patient D during a cardiac stent procedure, Dr. Shapira erroneously injected 20cc of air into the 6 French arterial sheath of the right radial artery (i.e., into the wrong port), causing the patient to lose voluntary movement of his left upper extremity and became unresponsive. A stroke alert was initiated, a nurse called a hospital Code, and Patient D was placed on a ventilator. Subsequently, Patient D was transferred to a North Carolina hospital where he was diagnosed with hypoxic respiratory failure, pulmonary edema, and a cerebral air embolism, for which he underwent hyperbolic therapy.

g. The following day, on May 28, 2019, the hospital suspended all of Dr. Shapira's clinical privileges. On July 3, 2019, while under investigation by the hospital's Medical Executive Committee, Dr. Shapira agreed to relinquish voluntarily his cardiac catheterization lab clinical privileges. On said date, the hospital lifted the precautionary suspension of Dr. Shapira's medical clinical privileges, allowing him to resume exercising his medical cardiology (non-invasive) privileges, effective July 9, 2019.

7. In the July 23, 2020 *Consent Order*, Defendant admitted to the "Findings of Fact and Conclusions of Law" recited above, and waived his right to contest the same in any future proceeding

III. VIOLATIONS

A. Based on the foregoing, Defendant is guilty of unprofessional conduct as follows:

a. Disciplinary action of another state or jurisdiction against a license or other authorization to practice medicine and surgery based upon acts of conduct by the licensee similar to acts or conduct that would constitute grounds for action as defined in this section, a certified copy of the record of the action taken by the other state or jurisdiction being conclusive evidence thereof, in violation of Okla. Admin. Code § 435:10-7-4(31).

b. Conduct likely to harm the public, in violation of 59 O.S. §509(8) and Okla. Admin. Code § 435:10-7-4(11).

c. Being physically or mentally unable to practice medicine and surgery with reasonable skill and safety, in violation of Okla. Admin. Code § 435:10-7-4(17).

V. CONCLUSION

Given the foregoing, the undersigned respectfully requests the Board conduct a hearing, and, upon proof of the allegations contained herein, impose such disciplinary action as authorized by law, up to and including suspension or revocation and any other appropriate action with respect to Defendant's professional license, including an assessment of costs and attorney's fees incurred in this action as provided by law.

Respectfully submitted,

Amanda E. Everett, OBA # 30107
Assistant Attorney General
OKLAHOMA STATE BOARD OF MEDICAL
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101 N.E. 51st Street
Oklahoma City, Oklahoma 73105
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VERIFICATION

I, Melissa Davis, RN, under penalty of perjury, under the laws of the State of Oklahoma, state as follows:

1. I have read the above Complaint regarding **SHMUEL SHAPIRA, MD**, and,
2. The factual statements contained therein are true and correct to the best of my knowledge and belief.

M Davis, RN

Melissa Davis, RN
OKLAHOMA STATE BOARD OF MEDICAL LICENSURE AND SUPERVISION

Executed this 28 day of January, 2021, in Oklahoma County, State of Oklahoma.